SECTION 5 - 510(k) Summary

OCT - 7 2011

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: K110780

Submitter SEPPIM S.A.S.
Address Zone Industrielle, 61500 SEES, FRANCE
Phone number + 33 (0)2 33 81 21 00
Fax number + 33 (0)2 33 28 77 51

Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Debra K. Hutson (email: d.hutson@elitechgroup.com)

Date of Preparation Sept 9, 2011

Device names

REAGENT:

Trade/proprietary Name:	**ELITech Clinical Systems BILIRUBIN TOTAL 4+1**
Common or Usual Name:	Bilirubin total, **"BILIRUBIN TOTAL 4+1"**
Device Class	Class II
Classification name	Bilirubin (Total or Direct) test System (Sec.862.1110)
Product code	**CIG** – Diazo Colorimetry, Bilirubin

Predicate device ABX PENTRA BILIRUBIN, TOTAL CP (K060325)

Device description The device for this submission is available as kit only. It consists of 2 reagents, "R1" and "R2".
Reagent R1 contains sulfanilic acid, Hydrochloric acid and cetrimide.
Reagent R2 contains sodium nitrite.

Intended Use ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.
It is not intended for use in Point of Care settings.

Indication for use Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block

Comparison to Predicate device

	ELITech Clinical Systems Device BILIRUBIN TOTAL 4+1	Predicate device (ABX PENTRA BILIRUBIN, TOTAL CP K060325)
Intended use	Intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	Intended for use with associated calibrators and controls for quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ABX PENTRA 400 Clinical Chemistry Analyzer.
Indication for Use	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.
Assay protocol	Malloy-Evelyn modified method	Photometric test using 2,4-dichloroaniline (DCA) and a specific mixture of detergents
Composition	Reagent 1 : Sulfanilic acid 29 mmol/L Hydrochloric acid 67 mmol/L Cetrimide 37 mmol/L Reagent 2 : Sodium nitrite 5.8 mmol/L	Reagent 1 : Phosphate buffer 50 mmol/L NaCl 150 mmol/L Detergents , Stabilizers Reagent 2 : 2,4-Dichlorophenyl – diazonium salt 5 mmol/L HCl 130 mmol/L Detergent
Appearance of reagent	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Lithium heparin plasma	Serum Plasma in lithium heparin
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8°C and contamination is avoided.
Expected values	Adults: 0.3 – 1.2 mg/dL	Adults : 0.1 – 1.2 mg/dL
Instrument	Selectra ProM	ABX PENTRA 400
Measuring range	0.28 to 20.22 mg/dL	0.2 to 26.3 mg/dL
Limit of detection (LoD)	0.06 mg/dL	0.09 mg/dL
Limit of quantification (LoQ)	0.17 mg/dL	0.14 mg/dL
Precision	**Within run** Level 1.04 mg/dL CV=2.7% Level 3.67 mg/dL CV=0.8% Level 14.90 mg/dL CV=0.5%	**Within run** Level 0.97 mg/dL CV=2.14% Level 5.13 mg/dL CV=0.99% Level 0.61 mg/dL CV=3.09% Level 0.85 mg/dL CV=2.23% Level 2.20 mg/dL CV=1.33% Level 8.35 mg/dL CV=0.83%

	ELITech Clinical Systems Device BILIRUBIN TOTAL 4+1	Predicate device (ABX PENTRA BILIRUBIN, TOTAL CP K060325)
	Total Level 1.04 mg/dL CV=4.0% Level 3.67 mg/dL CV=2.0% Level 14.90 mg/dL CV=1.8%	**Total** Level 1.0 mg/dL CV=4.04% Level 5.5 mg/dL CV=1.70% Level 0.8 mg/dL CV=5.97% Level 2.9 mg/dL CV=2.78% Level 9.1 mg/dL CV=2.20%
Method comparison	y=0.924x + 0.02 mg/dL r^2= 0.998 range: 0.25 to 22.00 mg/dL	y=1.03x – 0.14 mg/dL r^2= 0.9965 range: 0.3 to 25.8 mg/dL
Limitations	**Triglycerides** No significant interference up to 2779 mg/dL **Hemoglobin:** No significant interference up to 500 mg/dL . **Acetaminophen:** No significant interference up to 30 mg/dL . **Ascorbic acid:** Concentrations greater than 2.0 mg/dL will interfere and cause erroneous results. **Acetylsalicylic acid:** No significant interference up to 200 mg/dL	**Hemoglobin:** No significant influence is observed up to 500 mg/dL. **Triglycerides:** No significant influence is observed up to 612.5 mg/dL (as Intralipid®, representative of lipemia).
Calibration Frequency	28 days	10 days
On board stability	refrigerated area : 28 days	refrigerated area: 25 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

Device names

REAGENT:

Trade/proprietary Name:	**ELITech Clinical Systems BILIRUBIN DIRECT 4+1**
Common or Usual Name:	Bilirubin direct, **"BILIRUBIN DIRECT 4+1"**
Device Class	Class II
Classification name	Bilirubin (Total or Direct) test System (Sec.862.1110)
Product code	**CIG** – Diazo Colorimetry, Bilirubin

Predicate device ABX PENTRA BILIRUBIN, DIRECT CP (K060325)

Device description The device for this submission is available as kit only. It consists of 2 reagents, "R1" and "R2".
Reagent R1 contains sulfanilic acid and Hydrochloric acid.
Reagent R2 contains sodium nitrite.

Intended Use ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is intended the quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.
It is not intended for use in Point of Care settings.

Indication for use Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block

Comparison to Predicate device

	ELITech Clinical Systems Device BILIRUBIN DIRECT 4+1	Predicate device (ABX PENTRA BILIRUBIN, DIRECT CP K060325)
Intended use	Intended for the quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	Intended for use with associated calibrators and controls for quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma on ABX PENTRA 400 Clinical Chemistry Analyzer.
Indication for Use	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block	Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block
Assay protocol	Malloy-Evelyn modified method	Photometric test using 2,4-dichloroaniline (DCA)
Composition	Reagent 1 : Sulfanilic acid 29 mmol/L Hydrochloric acid 67 mmol/L	Reagent 1 : Sulfamic acid 100 mmol/L EDTA-Na_2 0.1 mmol/L NaCl. 150 mmol/L

	ELITech Clinical Systems Device BILIRUBIN DIRECT 4+1	Predicate device (ABX PENTRA BILIRUBIN, DIRECT CP K060325)
	Reagent 2 : Sodium nitrite 5.8 mmol/L	Reagent 2 : 2,4-Dichlorophenyl – diazonium salt 0.5 mmol/L HCl 900 mmol/L EDTA-Na_2 0.13 mmol/L
Appearance of reagent	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Lithium heparin plasma	Serum Plasma in lithium heparin
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8°C and contamination is avoided.
Expected values	< 0.2 mg/dL	≤ 0.2 mg/dL
Instrument	Selectra ProM	ABX PENTRA 400
Measuring range	0.18 to 6.82 mg/dL	0.09 to 6.71 mg/dL
Limit of detection (LoD)	0.06 mg/dL	0.04 mg/dL
Limit of quantification (LoQ)	0.17 mg/dL	
Precision	**Within run** Level 0.49 mg/dL CV=2.0% Level 1.89 mg/dL CV=0.6% Level 4.96 mg/dL CV=0.5% **Total** Level 0.49 mg/dL CV=4.7% Level 1.89 mg/dL CV=3.3% Level 4.96 mg/dL CV=3.2%	**Within run** Level 0.90 mg/dL CV=0.67% Level 1.85 mg/dL CV=0.44% Level 0.23 mg/dL CV=3.23% Level 1.52 mg/dL CV=0.59% Level 7.88 mg/dL CV=2.69% **Total** Level 0.94 mg/dL CV=4.26% Level 2.02 mg/dL CV=4.22% Level 0.69 mg/dL CV=3.27% Level 3.83 mg/dL CV=2.98%
Method comparison	y=0.988x + 0.07 mg/dL r^2= 0.974 range: 0.10 to 6.23 mg/dL	y=1.06x + 0.04 mg/dL r^2= 0.9928 range: 0.09 to 6.71 mg/dL
Limitations	**Triglycerides** No significant interference up to 2106 mg/dL **Hemoglobin:** No significant interference up to 125 mg/dL . **Acetaminophen:** No significant interference up to 30 mg/dL. **Ascorbic acid:** Concentrations greater than 0.3 mg/dL will interfere and cause erroneous results. **Acetylsalicylic acid:**	**Hemoglobin:** do not use hemolyzed samples **Triglycerides:** No significant influence is observed up to 612.5 mg/dL (As Intralipid®, representative of lipemia)

	ELITech Clinical Systems Device BILIRUBIN DIRECT 4+1	Predicate device (ABX PENTRA BILIRUBIN, DIRECT CP K060325)
	No significant interference up to 200 mg/dL	
Calibration Frequency	28 days	10 days
On board stability	refrigerated area : 28 days	refrigerated area: 30 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

Device Names

CALIBRATOR:

Trade/proprietary Name:	**ELITech Clinical Systems ELICAL 2**
Common or Usual Name:	Calibrator, multi-analyte mixture, **"ELICAL 2"**
Device Class	Class II
Classification name	Calibrator (21 CFR 862.1150)
Product code	JIX- Calibrator, multi-analyte mixture

Predicate device Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

Device description ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the ELITech Clinical Systems Selectra analyzers.	For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date *After reconstitution, the stabilities are :* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C: 8 hours Between -25 and -15 °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between -25 and -15 °C: 2 weeks (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)

Device names

CONTROLS:

Trade/proprietary Name:	**ELITech Clinical Systems ELITROL I and ELITROL II**
Common or Usual Name:	Multi-analyte controls – all kinds, **"ELITROL I"- "ELITROL II"**
Device Class	Class I
Classification name	Quality control material (assayed and unassayed). (21 CFR 862.1660)
Product code	JJY- Multi-analyte controls – all kinds

Predicate device Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

Device description ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.
Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for in vitro diagnostic use in quality control of ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device ELITROL I / ELITROL II	Predicate Device Roche Precinorm U / Precipath U K041227
Intended use	ELITech Clinical Systems ELITROL I and ELITROL II are a multi-parametric control sera for *in vitro* diagnostic use in quality control of ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.	For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet
Format	Lyophilized human sera with constituents added as required to obtain desired components levels	Lyophilized human sera with constituents added as required to obtain desired components levels
Levels	Two levels	Two levels
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open the bottle, avoiding the loss of lyophilizate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between -25 and -15 °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between -25 and -15 °C: 2 weeks (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

Conclusion

The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ELITech Group
c/o Debra Hutson
21720 23rd Dr. SE, Suite 150
Bothell, Washington 98021

OCT - 7 2011

Re: k110780
Trade Name: ELITech Clinical Systems Bilirubin Total 4+1,
ELITech Clinical Systems Bilirubin Direct 4+1,
ELITech Clinical Systems ELICAL 2,
ELITech Clinical Systems ELITROL I and ELITROL II
Regulation Number: 21 CFR §862.1110
Regulation Name: Bilirubin Test System
Regulatory Class: Class II
Product Codes: CIG, JIX and JJY
Dated: September 12, 2011
Received: September 14, 2011

Dear Ms. Hutson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k110780

Device Name: ELITech Clinical Systems BILIRUBIN TOTAL 4+1

Indications for Use:

ELITech Clinical Systems BILIRUBIN TOTAL 4+1 is intended for the quantitative *in vitro* diagnostic determination of total bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k110780

Indications for Use Form

510(k) Number (if known): K110780

Device Name: ELITech Clinical Systems BILIRUBIN DIRECT 4+1

Indications for Use:

ELITech Clinical Systems BILIRUBIN DIRECT 4+1 is intended for the quantitative *in vitro* diagnostic determination of direct bilirubin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

It is not intended for use in Point of Care settings.

Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110780

Indications for Use Form

510(k) Number (if known): K110780

Device Name: ELITech Clinical Systems ELICAL 2

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for in vitro diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110780

Indications for Use Form

510(k) Number (if known): K110780

Device Name: _____ ELITech Clinical Systems ELITROL I & ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth Chesler

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 110780